

2. RESPONSE/REMARKS

2.1 STATUS OF THE CLAIMS

Claims 8-19, 32-35, 39, 40 and 44-52 were pending at the time of the Action.

Claims 8, 19, 32, and 33 are amended herein.

Claims 8-19, 32-35, 39, 40, and 44-52 remain pending in the application.

Claims 32-35, 39, 40, 51, and 52 have been indicated as allowable by the present Action.

2.2 SUPPORT FOR THE CLAIMS

Complete support for the language of all pending claims can be found throughout the Specification and claims as originally filed. Applicants hereby certify that no new matter is incorporated because of the accompanying amendment.

Should any fees be deemed necessary in connection with the entry and consideration of the present paper the Assistant Commissioner is hereby authorized to deduct any necessary amounts from Deposit Account No. 08-1934, Order No. 36677.29.

2.3 WITHDRAWN OBJECTIONS AND REJECTIONS

Applicants appreciate the finding of the Examiner that the numerous claim objections and rejections set forth in the previous Action (enumerated in the present Action at page 2) have been withdrawn in light of Applicant's submission of June 5, 2006. Applicants also note for the record that no issues of prior art remain for any pending claims either under Section 102 or 103 of the *Code*, and that all claims have been found to meet the statutory requirement for utility as defined in 35 U. S. C. § 101.

2.4 RESPONSE TO PENDING REJECTIONS

Applicants incorporate herein by reference all arguments and reasoning presented in the earlier responses on record in the pending matter. It is respectfully submitted that the pending claims are fully enabled by the specification, that all pending claims are definite, and that all claims are free of the cited prior art. Applicants believe that the claims are acceptable under all sections of the Statutes and are now in conditions for ready allowance, and that all of the concerns of the Examiner have been resolved. Applicants respectfully request, therefore, the withdrawal of all rejections and that a Notice of Allowance be issued in the case with all due speed. However, Applicants note for the record their explicit right to re-file claims to one or more aspects of the invention as originally claimed in one or more continuing application(s) retaining the priority claim of the present case.

2.5 THE REJECTION OF CLAIMS 8, 12-19, AND 44-50 UNDER 35 U. S. C. § 112, 1ST PAR., IS OVERCOME.

The Action at pages 2-3 rejects claims 8, 12-19, and 44-50, allegedly as failing to comply with the written description requirement.

The Action reports the alleged deficiency in the Specification beginning in the third-from-last line of page 3:

“...the specification does not disclose the synthesis of any cyclic peptidomimetic compound in the claimed method, nor describes a genus of variants for cyclic peptidomimetic compounds.”

This alleged deficiency in the application is further defined by the Office in the middle of the first paragraph of page 4 of the Action:

“....the specification does not describe the use of various A1 and A2 in the synthesis of any cyclic peptidomimetic compound in the claimed method.

Furthermore, there are no examples indicating the use of A1 and A2 in the synthesis of cyclic peptidomimetic compounds. The lack of description on the synthesis of a cyclic peptidomimetic compound, and the lack of representative species as encompassed by the claims, (*sic*) applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.”

As to each of these assertions, the Applicants respectfully traverse.

Contrary to the Office’s assertion, Applicants respectfully point out that examples of peptidomimetic compounds synthesized by methods of the present invention are in fact disclosed in the specification.

In particular, Example 1 of the Specification discloses, *inter alia*, the cyclization of peptides in which there is backbone substitution (*M*-methylation) (see, *e.g.*, Table 3 at page 31). Sarcosine (Sar) is not a naturally-occurring amino acid.

Likewise, Example 4 discloses, *inter alia*, the cyclization of peptides which comprise the amino acid analogs aminocarboxythiophene (Act) and aminomethylbenzoic acid (Amb) (see, *e.g.*, Table 5 at page 65). Act is also known as 3-carboxy 4-aminothiophene (Cat), which is also depicted in Scheme 9 at page 64 of the Specification.

Additionally, Example 10 discloses, *inter alia*, the cyclization of peptides comprising β -alanine (see, *e.g.*, Table 7 at page 106).

The term “monomer” is defined for the purposes of the specification at page 22 (line 21) to page 23 (line 17). Applicants draw particular attention to page 23, lines 16 to 17, which states, “thus the word ‘peptide’ as used herein encompasses peptidomimetic compounds.” Exemplary compounds listed in the given definition include, but are not limited to: (a) biosynthetically-available amino acids that are not usually found in proteins, (b) Ca-N -alkylated amino acids, and

(c) amino acid analogs (*e.g.*, β -alanine, γ -aminobutyric acid, *etc.*) (see, *e.g.*, page 23, lines 4 to 16).

Applicants respectfully submit that the person skilled in the art would realize on the basis of a fair reading of the specification as a whole that the methods of the invention are useful in the synthesis of peptidomimetic compounds. Such a person would also realize that the methods of the invention are generally applicable, and are not limited to the particular illustrative cyclic peptides and peptidomimetic compounds that are specifically exemplified in the various Examples provided in the Specification.

Applicants believe this fully addresses the concerns of the Examiner, and respectfully requests, therefore that the rejection be withdrawn.

2.6 THE REJECTIONS OF CLAIMS 8-19 AND 44-50 UNDER 35 U. S. C. § 112, 2ND PAR., ARE OVERCOME.

The Action at pages 4-5 rejects claims 8-19 and 44-50 under 35 U. S. C. § 112, 2nd paragraph, allegedly as being indefinite.

As to each of these rejections, Applicants respectfully traverse.

At page 5 of the Action, Item 7, claim 8 remains rejected allegedly for indefiniteness. Applicants respectfully traverse. However, in an effort to expedite the allowance of particular claims, and without acquiescing in any way to the propriety of the rejection, Applicants have clarified the language of claim 8 which initially read “in which the cycle is a monocycle, bicycle or higher order cycle comprising 1 to 15 monomers.” Sub-paragraph (a) of claim 8 now recites the phrase “in which the cycle is a monocycle, bicycle or higher order cycle comprising 2 to 15 monomers,” and step (d) of the method now recites the phrase “a cyclic peptide or peptidomimetic compound of General Formula I or General Formula II.”

Applicants believe this addresses the concern raised by the Examiner and respectfully requests that the rejection now be withdrawn.

Further, at page 5 of the Action, Item 8, claim 19 is considered indefinite because of the use of the terms “substituted alkyl” and “substituted heteroaryl” R₃, R₄ and R₅.

Again, Applicants respectfully traverse; however, without acquiescing in any way to the propriety of the rejection, and solely in order to progress prosecution of particular claims of commercial importance to immediate allowance, Applicants have further clarified the language of claim 19 to improve its clarity and to more particularly point out certain aspects of the invention.

Applicants believe that this clarification fully addresses the concerns of the Examiner, and respectfully requests, therefore that the rejection be withdrawn.

Finally at page 5 of the Action, Item 9, claims 46 and 48 were rejected for indefiniteness allegedly because “the structures of A2 in the claim contain an NH group, while A2 (e.g., 6-nitro-2-hydroxybenzyl) should not contain an NH group, which belongs to the peptide.”

Applicants again respectfully traverse this rejection, and note for the record that the structures of A2 shown in the claim are based on the examples of ring contraction auxiliaries shown on page 36 of the specification. In these structures R' represents the peptide. In other words, the diagram (with R') reflects the state of the system *prior to ring contraction*, but after the auxiliary is attached to the peptide. The examples of A2 shown in claims 46 and 48 are not exactly the same as on page 36, because they lack R'. The structures in the claims do show an NH-group. Thus, the structures again represent the system *prior to ring contraction*, *i.e.*, the peptide with auxiliary attached. Claims 46 and 48 are respectively directly and indirectly

dependent on claim 8. Because general formulae III-V show A2 attached to the peptide P, claims 46 and 48 are fully consistent with, and properly dependent upon, claim 8.

As an example, one means of attaching the auxiliary to the N-terminus of the peptide is *via* reductive amination, in which case the auxiliary would have an aldehyde to undertake this reaction. The person skilled in the art would be well aware of other ways of attaching the auxiliary given the benefit of a fair reading of the specification as filed.

Applicants believe that this clarification fully addresses the concerns of the Examiner, and respectfully requests, therefore that the rejection be withdrawn.

2.7 CONCLUSION

Applicants believe this to be a full, timely, and complete response to the referenced Action. It is respectfully submitted that the pending claims are now fully acceptable under all sections of the Statutes and are now in conditions for ready allowance, and that all of the previous concerns of the Examiner in the pending application have now been satisfactorily resolved. Applicants further respectfully request, therefore, the withdrawal of all rejections and that a Notice of Allowance be issued in the case with all due speed.

Should any issues remain in the mind of the Examiner, or should any claims remain rejected for any reason following entry of the present amendment and consideration of the remarks and response herein, Applicants respectfully request that pursuant to M. P. E. P. §§ 408 and 713.09, the Examiner contact the undersigned representative to arrange a telephonic Examiner Interview at a mutually convenient time to discuss favorable disposition of the case and the resolution of any remaining issues of record.

Applicants also note for the record their explicit right to re-file claims to one or more aspects of the invention as originally claimed in one or more continuing application(s) retaining the priority claim from the present and parent cases.

Should the Examiner have any questions, a telephone call to the undersigned Applicants' representative would be appreciated and in particular in advance of any subsequent action on the merits.

Respectfully submitted,



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